REMARKS

A. In the Election/Restriction

Claims 1-35 have been held to be pending and subject to the Office Action. Claims 14-20 of Group II have been held to have been elected without traverse, and the addition of claims 21-35 as part of Group II has been acknowledged.

The Examiner has stated that claims 17 and 18 have been canceled. In the Amendment of November 9, 2006, Applicant has not canceled claims 17 and 18 but instead has withdrawn claims 17 and 18 from examination. Therefore, Applicant submits that claims 17 and 18 are presently pending in the application but have been withdrawn from examination.

B. In the Specification

1. Sequence Listing

A sequence listing, inclusive of a CD, a paper copy, and a statement under 37 CFR 1.821(f) and (g) has been requested by the Examiner and are enclosed herein.

No entry of the SEQ ID Nos. is made in the Brief Description of the Drawings section of the application, because no sequence listing appears in the figures.

2. Title of the Invention

The title of the invention has been held not to be properly descriptive. In response, the title has been amended to recite: "Kit for inhibiting restenosis in a patient and method of use."

Although Applicant believes that the previous title is properly descriptive, the amendment to the title has been introduced to expedite allowance of the application and without restrictive intent.

3. Other Informalities

The word "us" has been corrected to "is" in claim 29, line 2.

B. In the Claims

Claims 1-35 are pending in the application. Claims 1-13 and 17-18 have been withdrawn from consideration. Claim 14 has been amended. Therefore, upon entry of the present amendment, claims 14-16 and 19-35 will be subject to examination.

1. The Rejections under 35 USC 112, First Paragraph

Claims 14-16 and 21-35 have been rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement. Applicant respectfully traverses this rejection because unsupported in law and in fact.

It is well settled in the law that an applicant is entitled to a patent if he has described an apparatus or process with adequate specificity, so that a person skilled in the art can reproduce the invention, even if the applicant does not understand why the apparatus or process produces those results. *Diamond Rubber Co. of New York v. Consolidated Rubber Tire Company*, 220 US 428 (1911) ("it is certainly not necessary that he understand or be able to state the scientific principles underlying his invention").

The function of the written description requirement is to ensure that the inventor had possession, on the filing date of the application, of the specific subject matter claimed; how the specification accomplishes this is not material. *In re Herschler*, 591 F.2d 693, 700-01, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in *In re Kaslow*, 707 F.2d 1366, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983). See also MPEP 2161.01.I.

In claims involving chemical materials, generic formulae usually indicate with adequate specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Examiner has rejected claim 14 alleging that exemplary molecular entities described at paragraph [0244] and table 10 of the published application, and that the statement at paragraph [0237],

> A restenosis inhibitory agent or moiety is a molecular entity (i.e., nucleus, atom, ion, molecule, compound, substance, or drug) capable of inhibiting restenosis by a mechanism, *even if unknown*, distinct from that of emission of radioactivity

provide insufficient written description to support the genus of claim 14, because the restenosis inhibiting moiety is not sufficiently and completely disclosed.

As best understood by Applicant, the Examiner's argument is related to the second element of claim 14, in particular, to the recitation "restenosis-inhibiting moiety." On the contrary, Applicant believes that the identification of restenosis-inhibiting moieties is supported in various paragraphs of the specification. The examples provided hereinafter are to be considered only illustrative and non-limiting.

Paragraphs [0237]-[0240] summarize known mechanisms of cell proliferation, which is the biological process underlying restenosis. Paragraphs [0240]-[0243] summarize mechanisms for preventing cell proliferation ([0240]-[0241]) and, more particular, restenosis ([0242]-[0243]). Paragraph [0243] and Table 10 list specific chemical compounds suitable for the purpose of claim 14. Therefore, the recitation "restenosis-inhibiting moiety" is fully supported in the specification, because the mechanisms underlying restenosis, mechanisms for preventing restenosis, and compounds inhibiting restenosis were properly disclosed.

The Examiner has argued that the statement in the application, that the specific mechanism causing a substance to inhibit restenosis may even be unknown in certain embodiments of the invention, provides proof of insufficient written description. Applicant notes that the written description requirement of claim 14 is met if Applicant "had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her; how the specification accomplishes this is not material." In the instant case, the described kit inhibits restenosis, and the Examiner has not argued the contrary. Therefore, Applicant had possession of which moieties inhibit restenosis, and how those moieties accomplish their purpose is not material for the purpose of patentability.

The Examiner has argued instead that failing to understand the mechanism of inhibiting restenosis, even if only in certain embodiments of the invention, vitiates the written description requirement. As discussed above, this is not material to patentability, because it is not necessary that Applicant understands or is able to state the scientific principles underlying his invention.

The generic formulae provided at paragraph [0243} and Table 10 indicate with specificity what claim 14 encompasses.

Other examples of restenosis-inhibiting compounds are mentioned in the specification, among others, at paragraph [0171], which contains a list of scientific references incorporated by reference. The mentioned compounds are not "potential compounds," as argued by the Examiner is arguing, but proven restenosis-inhibitors with identified chemistries. As an additional example, with reference to Table 10, nitric oxide is a proven restenosis-inhibitor, see e.g. U.S. patents nos. 5,650,447; 5,665,077; 5,904,938; 6,063,407; tetanus toxin is a proven restenosis-inhibitor, see e.g. U.S. patent nos. 5,739,169 and 6,290,949; diphteria toxin is a proven restenosis-inhibitor, see e.g. U.S. patent no. 6,290,949; and so on.

The Examiner has cited *Fiers v. Revel*, 25 USPQ2d 1601 (Fed. Cir. 1993) to support her contention that disclosure by Applicant is inadequate. Applicant submits that this citation is inapposite. The disputed claim in *Fiers* read: "A DNA which consists essentially of a DNA which codes for a human fibroplast interferon-beta polypeptide." The Court held: "An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1606. In the instant case, Applicant has identified a description of each of the restenosis-inhibiting compounds that enables one skilled in the art to identify the specific chemistries, rather than providing a non-specific description as in *Fiers*.

Claims 14-16 and 21035 have also been rejected under 35 USC 112, first paragraph for allegedly failing to comply with the written description requirement by claiming an expanding tubular structure rather than a stent, as described in the specification. While the Examiner has acknowledged that a stent is an expanding tubular structure, the Examiner has argued that the description in the specification of a single species of tubular structure is insufficient to provide support to the broader recitation of "expanding tubular structure."

Paragraph [0064] of the published application states, in relevant part:

> numerous types of medical devices may usefully be made radioactive, or otherwise capable of inhibiting unwanted cellular growth. Examples include but are not limited to stents, coils, shunts, pins, plates, meshes, particles, spheres, vascular grafts, artificial valves, artificial joints, cannulas, orthopedic burs, catheters, electrode leads, filters,

needles, prostheses, and patches. Additional medical devices useful for purposes of the present invention are within the knowledge of the skilled artisan.

Therefore, Applicant has directly mentioned the applicability of the invention to devices other than stents. While Applicant acknowledges that the only medical device described in detail is a stent, Applicant fails to understand why a person skilled in the art could not apply the described techniques, for example, to a shunt for draining bodily fluids, or to a vascular graft. Applicant submits instead that all such embodiments are within the purview of a person skilled in the art, because, for example, the description of Example I at paragraphs [0338]-[0340] are equally valid if the word "stent" was replaced with "shunt." Additionally, Applicant submits that a stent is inherently "an expanding tubular structure," as the Examiner has acknowledged. Further, Applicant respectfully directs the Examiner to U.S. patent no. 5,871,436 to Eury, cited by the Examiner and discussed in the following section. The only embodiment described by Eury is a stent, yet claim 4 is directed to "an intravascular medical device."

In order to expedite allowance of the application and without restrictive intent, as indicated by the foregoing discussion, Applicant has amended claim 14 to recite "an intravascular medical device" instead of "an expanding tubular structure," as in the *Eury* reference.

Claim 25 has also been rejected under 35 USC 112, first paragraph because the linker moiety is allegedly described in broad terms by stating that the "linker may comprise" certain compounds. As stated in various points of the specification, linker chemistry and activity is known in the art. Paragraph [0073], cited by the Examiner, begins by stating "According to the knowledge of the skilled artisan, linker 12 may comprise ..." Specifics on the structure and composition of linkers are also discussed, among pothers, at paragraph [0076], which cites a learned treatise incorporated therein by reference. Therefore, a person skilled in the art would recognize the necessary linker based on Applicant's description.

Applicant further submits that the use of the term "may" is common in patent drafting to indicate that an element can be selected within a range known to a person skilled in the art. To prove this point, the Examiner is respectfully directed to col. 4, lines 21-35 of the *Eury* reference: "The base layer *may* comprise gold or any organic coating that contains a nucleophile, or

potential nucleophile. These sites *could potentially* be aliphatic ... *Possible* base layers include polyurethane ..." (Emphasis added).

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"); see also MPEP 2163.I.A. Applicant submits that the Examiner has not provided evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by claim 25.

The Examiner also has argued that the alleged failure to provide proper disclosure of the linker claimed in claim 25 provides inadequate support to claim 14 as well. Applicant notes that the linker is an element that is not a recited nor inherent in claim 14, therefore, that any rejection related to the "linker" recitation must be limited to claim 25.

Finally, the Examiner has cited *Fiers v. Revel*, *supra* to support her argument of inadequate written description. Applicant submits that this citation is inapposite, for the same reasons as discussed previously.

B. The Rejections under 35 USC 103(a)

Claims 14-16 and 19-23, and 28-35 have been rejected under 35 USC 103(a) as allegedly obvious over U.S. patent no. 5,871,436 to Eury ("*Eury*") in view of U.S. patent nos. 5,871,437 to Art ("*Art*") and 5,873,811 to Wang et al. ("*Wang*"). Although number 5,924,973 also appears in the same paragraph where the various patent numbers are listed, this number has not been considered by Applicant because the context of the sentence indicates that number was cited inadvertently and because this number was not listed in the "Notice of References Cited." The rejection of claims 14-16 and 19-23, and 28-35 under 35 USC 103(a) is traversed at least for the following reasons.

Eury is directed to an implantable medical device delivering a dosage of radiation to a localized site within a patient. In particular, *Eury* teaches: "Just prior to implantation, the stent is immersed in the vial in order to allow the chelator to absorb the radioisotope." *Eury*, Abstract; Col. 5, lines 2-5.

Therefore, *Eury* requires that the stent be immersed into a radioisotope, provided in a suspension contained in a vial, that is suitable for dipping prior to implantation. *Eury* does not teach or suggest "a restenosis-inhibiting moiety configured for administration to the patient after implantation of the stent in the vessel," as recited in Applicant's amended claim 14.

Alt and *Wang* do not resolve the deficiencies of *Eury*. *Alt* is directed to a stent having a coating that contains a radioactive source of beta emitting properties for irradiation of tissue when the stent is implanted in a patient's vessel. The product containing the radioactive source is configured for coating prior to implantation of the stent, and is not "a restenosis-inhibiting moiety configured for administration to the patient after implantation of the stent in the vessel," as recited in Applicant's amended claim 14. See, e.g., *Alt*, Abstract; col. 7, lines 39-53; col. 9, lines 1-24.

Wang is directed to a biologically compatible adhesive that includes a radioactive material applied to the vessel region where inhibition of restenosis is desired. *Wang*, Abstract; Summary of the Invention. Therefore, *Wang's* adhesive is configured to bond to the vessel wall and is not configures to bond to the stent surface, because it does not include "a second member of the specific binding pair capable of binding to the first member," as recited in Applicant's claim 14.

Claims 15-16 and 19-35 all depend from claim 14, directly or indirectly, and are allowable over the cited prior art at least for the same reasons as independent claim 14.

C. Timeliness of the Present Filing

The 3-month deadline for foiling a response expired on April 22, 2007, which was a Sunday. Because this response is being filed on the successive Monday, this response is considered timely,

D. Conclusion

Based on the foregoing, Applicants submits that the present application is in condition for allowance and respectfully requests the timely issue of a notice to that effect.

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Respectfully submitted,

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